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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,872	12/04/2000	Tony Wai-Chiu So	C7979U	5826

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EXAMINER	
WELTER, RACHAEL E	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
10/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/673,872	WAI-CHIU SO ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,8,12-16,19,21,23,24,26,29 and 139-161* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,8,12-16,19,21,23,24,26,29 and 139-161* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Application/Control Number: 09/673,872
Art Unit: 1611

DETAILED ACTION

Claim Status

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161 are pending. Claims 2, 5-7, 9-11, 17-18, 20, 22, 25, 27-28, and 30-138 are cancelled.

Acknowledgements

Receipt of the amendment and arguments/remarks filed on 7/26/10 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Application/Control Number: 09/673,872
Art Unit: 1611

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, 139, 141-144, 146-151, and 153-160 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of Yu et al (EP0273202) is maintained.

Peck teaches a quick breaking foam to treat baldness comprising (a) 1-**5**% minoxidil; (b) **10**-50% propylene glycol; (c) 30-75% alcohol; (d) 0.5-10% emulsifier and/or surfactant; (e) 0.1-5% hydroxypropyl methylcellulose; and (f) 10-50% water wherein the composition is actuated with a propellant. See page 2. Peck teaches the minoxidil may be selected from any known analog. Peck teaches skin penetrates including alcohol such as dodecanol and oleyl alcohol. See page 5. Peck teaches various surfactants in the composition including Tween 80 (polysorbate) and Span 60 to improve the stability of the composition. See page 6, lines 20-25. Included in the class of emulsifiers is lauryl alcohol, isostearyl alcohol, and cocamide DEA. See page 6, lines 10-17. Peck teaches the use of minoxidil or a salt thereof. See page 5, lines 25-30.

Application/Control Number: 09/673,872
Art Unit: 1611

Propellants taught by Peck include hydrocarbons, such as propane, isobutene, or dimethyl ether and chlorofluorocarbons. See page 6, lines 2-6.

Peck does not teach the instant acid salt.

Yu et al teach additives such as hydroxy acids enhance the therapeutic effects of pharmaceutical and cosmetic actives in topical treatments. See page 2. The pharmaceutical or cosmetic active is utilized generally in the amount of 0.01-40% and the hydroxyl acid is used in the amount of 0.01-99%. See page 6. Yu teaches the use of 3% lactic acid with minoxidil to help the minoxidil dissolve in the solution and enhance penetration and the efficacy of minoxidil on hair growth. The pH of the solution is 4.7. See example 3.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teaching of Peck and Yu et al and utilize the instant acid. One would be motivated to do so since Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, a skilled artisan would have been motivated to add an acid to form a minoxidil acid salt for enhanced penetration of minoxidil into the hair follicle.

Regarding the recitations of “at least 5%” of minoxidil salt and 7.5 to 12% by weight, Peck teaches minoxidil in an amount of 1-5%. “At least 5%” includes 5.00001%, 5.001%, etc, which is considered obvious over the prior art’s “5%”. Furthermore, it would have been obvious to a skilled artisan at the time the invention was made to manipulate the concentration of minoxidil during routine optimization in order to achieve

Application/Control Number: 09/673,872
Art Unit: 1611

a concentration of 7.5 to 12% by weight. One would have been motivated to do so depending on the desired "strength" of the composition and to meet the needs of a particular patient population. Drug concentration is a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).*

Regarding the instantly claimed ratio of ethanol to water, Peck sets forth a general range of components wherein the alcohol is utilized in an amount of 30-75% and water from 10-50%, thus it is within the skill of an artisan to look at the guidance provided by Peck and manipulate the concentrations (ratio) of water and ethanol depending on the concentration of the other components. It should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).*

Regarding the instant pH of the final product, Yu suggests a minoxidil composition with a pH of 4.7, which reasonably reads on a pH of "approximately 5.0-7.0." Furthermore, it would have been obvious to incorporate a pH within the range of 5.0-7.0 in the composition of Peck because its compositions are administered to the skin/scalp and such a neutral pH range would not be harmful and/or irritating.

Response to Arguments

Application/Control Number: 09/673,872
Art Unit: 1611

Applicant's arguments filed 7/26/10 have been fully considered but they are not persuasive. The examiner directs applicant's attention to the Non-Final Office Action mailed 3/3/10 addressing applicant's arguments regarding the applied references above. The examiner's arguments are incorporated herein.

Applicant further submits a 1.132 Declaration by John Richard Buchta demonstrating commercial success of the presently claimed pharmaceutical composition. According to the Declaration, Rogaine foam's market share in the US has increased nearly six times in less than 4 years since its launch in 2006. Applicant further presents positive consumer responses on Amazon.com and an article describing consumer use studies. According to the consumer studies, minoxidil foam was rated significantly higher on several aesthetic attributes compared to minoxidil solution. Applicant further argues they are not required to compare commercial success with the closest prior art (Peck). Applicant argues the examiner is confusing commercial success with unexpected results. Applicant argues they have shown results with market share data and they do not need to show commercial success for every propylene glycol amount claimed. Furthermore, applicant argues they have established a nexus by showing the claimed features are responsible for Rogaine foam's commercial success.

Although the examiner acknowledges that applicant does not have to compare commercial success to the closest prior art, the 1.132 Declaration is insufficient for the following reasons:

Application/Control Number: 09/673,872
Art Unit: 1611

The instant data does not constitute "hard evidence" of commercial success as required in MPEP 2145 since the scope of the comparison is insufficient and the data is not provided with sufficient specificity to clarify the variables involved (i.e. locations of sale for the instant and comparative products, number of advertising dollars invested in each product). Applicant is reminded that the bar is extremely high for providing commensurate "hard evidence". It is noted that MPEP 2145 states that “to be entitled to substantial weight, the applicant should establish a nexus between the rebuttal evidence and the claimed invention, i.e., objective evidence of nonobviousness must be attributable to the claimed invention. The Federal Circuit has acknowledged that applicant bears the burden of establishing nexus, stating:

> In the ex parte process of examining a patent application, however, the PTO lacks the means or resources to gather evidence which supports or refutes the applicant’s assertion that the sales constitute commercial success. C.f. Ex parte Remark, 15 USPQ2d 1498, 1503 ([BPAI] 1990) (evidentiary routine of shifting burdens in civil proceedings inappropriate in ex parte prosecution proceedings because examiner has no available means for adducing evidence). Consequently, the PTO must rely upon the applicant to provide hard evidence of commercial success.

In re Huang, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996). See also GPAC, 57 F.3d at 1580, 35 USPQ2d at 1121; *In re Paulsen*, 30 F.3d 1475, 1482, 31 USPQ2d 1671, 1676 (Fed. Cir. 1994)”.

Furthermore, since Rogaine/Hair Growth received the biggest market share out of all the hair loss products on the market, it is not clear whether the instant product (also Rogaine) is receiving higher sales because of its claimed features. More customers may be buying the instant foam because of the brand name rather than its

Application/Control Number: 09/673,872
Art Unit: 1611

superior properties. As such, applicant needs to provide data on advertising costs as well as information on where the products were sold.

Regarding applicant's provided positive consumer responses and Olsen article, such results are not convincing because such evidence is merely opinion. In the instant case, the positive consumer responses are only individual preferences of the instant product. It is noted that many of the response do not compare the foam product to other Rogaine products on the market. Additionally, applicant appears to be making an improper comparison given what is known in the prior art. Applicant appears to be comparing the consumer success of a minoxidil foam to a minoxidil solution. However, this is improper because the prior art (Peck) teaches a foam and as such, one would expect rather than unexpect the success as evidenced by Olsen. Furthermore, the instant claims are not commensurate in scope with the unexpected results. According to MPEP 716.02, whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In this case, the MTF does not contain any propylene glycol. However, the examiner notes that instant claims 1 and 21 recite that propylene glycol can be in an amount of up to 10%. It is noted that in order "To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill, 284 F.2d 955, 128 USPQ 197 (CCPA 1960).* Moreover, it is not clear if an acid

Application/Control Number: 09/673,872
Art Unit: 1611

is present in the MTF to solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt.

As such, absent any persuasive commercial success and evidence commensurate in scope with the instant claims, it is the position of the examiner that the teachings of Peck in view of Yu would lead one of ordinary skill in the art to arrive at the instantly claimed invention.

The rejection of claims 140, 145, 152, and 161 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of Yu et al (EP0273202) as applied to claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, 139, 141-144, 146-151, and 153-160 above and in further view of Uchikawa et al (5,156,836) is maintained.

The teachings of Peck and Yu have been set forth above.

Peck does not teach the elected glycerol co-solvent or the use of an antioxidant.

Uchikawa teaches a hair revitalizing composition that may comprise minoxidil. Uckikawa teaches conventional excipients used to formulate hair-revitalizing compositions include polyhydric alcohols such as glycerine and propylene glycol, antioxidants, etc. see column 4, lines 5-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute the exemplified propylene glycol with the instantly claimed glycerol and arrive at the

Application/Control Number: 09/673,872
Art Unit: 1611

instant invention. One would have been motivated to do so since Uchikawa teaches both propylene glycol and glycerol are polyhydric alcohols conventionally used in the art. Therefore, a skilled artisan would have expected similar results absent unexpected results by using any conventional polyhydric alcohol known in the art in the composition. Further, it would have been obvious for a skilled artisan to further utilize a conventional excipient such as an antioxidant as taught by Uchikawa to prevent oxidation.

Response to Arguments

Applicant's arguments filed 7/26/10 have been fully considered but they are not persuasive.

Applicant argues the merits of Peck and Yu and the commercial success established in the Buchta Declaration.

These arguments have been addressed above and are incorporated herein. It is noted that Uchikawa is only relied upon to teach the instant co-solvent and applicant has not argued this teaching.

As such, it is the examiner's position that the instant claims are rendered obvious over Peck, Yu, and in further view of Uchikawa.

Conclusion

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161 are rejected. No claims are allowed.

Application/Control Number: 09/673,872
Art Unit: 1611

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 09/673,872
Art Unit: 1611

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643